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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,480

06/20/2003

Frank A. Skraly

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06/27/2006

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,480	SKRALY ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed April 28, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 10, 11, and 13-19 are pending.

Election/Restrictions

3. In the reply filed on November 21, 2005, applicant elected with traverse 4-hydroxyvalerate for species A, bacteria for species B, polyhydroxyalkanoate synthase for species C, and poly (4-hydroxyvalerate) for species D. In view of applicant's arguments filed April 28, 2006, these species are now considered free of the art and claims drawn solely to these species would be considered allowable. The search has been extended to over the full scope of the claims; thus, all species have now been examined. As discussed in MPEP section 803.02:

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection...the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims...

4. Claims 10, 11, and 13-19 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 10, 11, and 13-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using bacteria to produce poly (3HB (hydroxybutyrate)-co-4HV (hydroxyvalerate)) from 4-HV, poly (4HV) from 4-HV, poly (5HV) from 5-HV, and poly (3HP (hydroxypropionate) -co-5HV) from 1,3 propanediol and 1,5 pentanediol does not reasonably provide enablement for producing poly (3HP), poly (3-HP-co-5HV) from any substrate other than 1,3 propanediol and 1,5 pentanediol, poly (3HB-co-4HV) or poly (4-HV) from any substrate other than 4-HV, and poly (5HV) from any substrate other than 5-HV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are drawn to a method of producing polymers in a biological system. Claim 10 lists substrates that can be used and specific polymers that are accumulated. However, applicant's specification does not teach how to make all of these polymers and does not teach that all of the claimed substrates can be used to accumulate the claimed polymers. Specifically, Example 1 of applicant's specification teaches that poly (3HB-co-4HV) accumulates when a biological system is given the substrate 4HV. The specification does not teach that the other substrates claimed can be used to accumulate this polymer. Example 2 of applicant's specification teaches that poly (4HV) accumulated when a biological system was given the

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substrate 4HV. The specification does not teach that the other substrates claimed can be used to accumulate this polymer. Example 5 of applicant's specification teaches that poly (3HP-co-5HV) accumulates when a biological system is given 1,3-propanediol and 1,5-pentanediol. The specification does not teach that any of the claimed substrates can be used to make this polymer. Example 6 of applicant's specification teaches that poly (5HV) accumulates with the use of 5-HV as the substrate. The specification does not teach using any other substrate to make this polymer. In addition, the specification does not teach how to make poly (3-HP). Thus, applicant's specification does not teach the full scope of the claimed invention.

The prior art teaches that the production of polymers in biological systems can be very unpredictable. For example, one of the substrates claimed by applicant is 4-hydroxyhexanoate (HHx). Valentin (*Appl Microbiol Biotechnol* (1994), vol. 40, pp. 710-6) teaches that when 4-HHx is used as a substrate, bacteria do not accumulate any of the claimed polymers. The reference also shows that the content of the accumulated polymer can be widely varied (see Table 1). In addition, Lee (*Appl Microbiol Biotechnol* (1995), vol. 42, pp. 901-9) teaches the composition of polymers created using many of the substrates claimed by applicant. Lee uses the same substrates as claimed but none of the polymers accumulated are the same as applicant's claimed polymers. Thus, the art shows that there is considerable unpredictability in the constitution of the polymers. Therefore, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if all of the claimed substrates can be used to make all of the claimed polymers. Based on this requirement for undue experimentation, applicant's claimed invention is not considered enabled for the full scope of the claims.

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6. No claims are allowed. However, allowable subject matter is indicated in paragraph 3.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

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Susan D. Coe
6-22-06

Susan D. Coe
Primary Examiner
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